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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| COE, SUSAN D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1654 | |

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/001,439 | MCANALLEY, BILL H. | |
| | Examiner | Art Unit | |
| | Susan D. Coe | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,8-20 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-20 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1, 8-20 and 24 are currently pending.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of intestinal pathogens and treatment of tumors, does not reasonably provide enablement for prevention of autoimmune response from intestinal pathogens, stimulation of gastrointestinal tract growth, prevention of tumor development and improvement in Alzheimer's dementia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claim 20 is broadly drawn to using the claimed composition of beta-glucan, colostrum, lactoferrin, citrus pectin, and essential saccharides for prevention of autoimmune response from intestinal pathogens, stimulating gastrointestinal tract growth, prevention of tumor

development, and improvement in Alzheimer's dementia. However, applicant's specification does not enable these uses of the composition. As discussed below in paragraph 3, the meaning of "prevention of autoimmune response from intestinal pathogen" is unclear. Since the meaning of this phrase is unclear, the specification clearly does not provide enough information for a person of ordinary skill in the art to practice this intended use of the composition. In addition, to be enabled for "prevention" of an autoimmune response, applicant must show that this response actually is prevented in every instance in scope with the claimed use. Applicant has not demonstrated that the claimed composition is able to prevent any sort of autoimmune response. In addition, it is well known in the art that it is very difficult to predict what will completely inhibit an immune response. Furthermore, autoimmune diseases caused by pathogens such as the HIV virus are well known to be impossible to completely prevent once infection has occurred. This is very well established. Thus, since "prevention" is known in the art to be difficult to predict and is not shown in the specification, applicant's claims are not considered enabled for the "prevention" of an autoimmune response.

Furthermore, applicant's claims are not considered enabled for "stimulation of gastrointestinal tract growth." Applicant has provided no examples that show that the claimed composition is able to make the gastrointestinal tract grow. Such a growth is difficult to measure and predict. Thus, since this applicant has not shown that the composition is able to successfully function in this manner and the art also does not support this use of the composition, the composition is not considered enabled for the ability to stimulate gastrointestinal tract growth.

Applicant's claims are also not considered enabled for the prevention of tumor development. In order to be enabled for the "prevention" of tumors, the composition must be

able to prevent tumor development in each and every instance. Applicant's specification does not demonstrate that the composition functions in this manner. In addition, prevention of cancer is known in the art to be extremely difficult to achieve. Prevention of types of cancer is known to not be absolute and depends on a variety of factors including the genetic make-up of the individual. Applicant clearly has not shown that the composition is able to prevent development of tumors and since it is known in the art that the prevention of tumors is very unpredictable, a person of ordinary skill in the art would clearly be forced to experiment unduly in order to determine if the composition is able to prevent tumor development.

In addition, applicant's claim is not considered to be enabled for improving Alzheimer's dementia. Alzheimer's disease is also a disease that is known to be extremely difficult to treat and impossible to prevent or cure. Applicant mentions a study on page 7 of the specification that showed that one component of colostrum is able to improve dementia resulting from Alzheimer's disease. However, applicant does not state the reference describing the study that is mentioned. In addition, applicant does not discuss the parameters of this study in any sort of detail. Thus, lacking support from the art and details of successful treatment, a person of ordinary skill in the art would be forced to experiment unduly to determine if the claimed composition is actually able to function in its intended use.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. In this claim, the phrase "prevention of autoimmune response from intestinal pathogens" is unclear. As stated the phrase reads as if the intestinal pathogens themselves are having an autoimmune response. However, this does not make logical sense. In addition, an immune response to an internal pathogen would not be an autoimmune response. It would be a normal immune response. It seems that applicant is intending to claim autoimmune diseases caused by pathogens; however, this is not clear.

***Claim Rejections - 35 USC § 103***

4. Claims 1, 8-20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,576,015, US Pat. No. 5,531,989, and WO 97/05884 for the reasons set forth in the previous Office action.

All of applicant's argument regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that because there are hundreds of ingredients known to strengthen the immune system there is no motivation in the art to select the specific ingredients claimed by applicant for combination. Applicant argues that the combination of the stated references is improper hindsight reasoning.

However, as discussed in MPEP section 2144.06 "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

US '015 teaches that beta-glucan from yeast cell walls enhances host immune resistance to diseases caused by bacterial and viral infection (see column 1, lines 20-38).

US '989 teaches that a composition comprising lactoferrin and fiber enhances the patients immune system and treats diseases caused by bacteria, viruses, fungi, and parasites (see column 3, lines 32-50). US '989 teaches that the fiber is from citrus pectin and from guar gum. Guar gum is specifically claimed by applicant in claim 19 as containing "essential saccharides." Thus, this reference shows that it was known in the art at the time of the invention that compositions containing lactoferrin, "essential saccharides," and citrus pectin enhance the immune system and also treat diseases caused by bacterial and viral infection.

WO '884 teaches that lactoferrin and colostrum strengthen the immune system (see page 3, second paragraph). In addition, this composition is taught to treat diseases caused by bacterial and viral infections (see page 2, last paragraph).

Thus, these references show that it was well known in the art at the time of the invention that all of the claimed ingredients, essential saccharides, lactoferrin, colostrum, and citrus pectin, were known to enhance a patient's immune response and to treat bacterial and viral infections. Since it has been well established that it is obvious to combine two or more ingredients that are known to be used for the same purpose, it is obvious to combine the compositions taught by the prior art into one composition. Motivation for such a combination stems from the teaching of equivalence of the ingredients in the art for the dual purposes of enhancing the immune system and treating bacterial and viral diseases.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the

time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Since the rejection is only based on what was known in the art at the time of the invention, improper hindsight was not used in this rejection.

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe, Examiner
November 15, 2004